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109TH CONGRESS
2D SESSION

H. R. 5280

To amend the Federal Food, Drug, and Cosmetic Act with respect to the distribution of the drug dextromethorphan, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 2006

Mr. UPTON (for himself and Mr. LARSEN of Washington) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the distribution of the drug dextromethorphan, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Dextromethorphan Distribution Act of 2006''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Dextromethorphan is a safe and effective active ingredient found in cough suppressant products sold over-the-counter in a variety of finished

dosage forms, including tablets, gel capsules, powders, and liquids.

(2) The bulk powdered form of dextromethorphan is readily available for purchase through various commercial channels.

(3) Individuals, including teenagers in particular, are attempting to get high by taking much larger than recommended doses of dextromethorphan.

(4) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the regulations of the Food and Drug Administration govern the sale of products containing dextromethorphan, the distribution of certain noncontrolled drugs of abuse, and the sale, purchase, trade, and distribution of drug products in general.

(5) One critical step that should be taken to help combat the abuse of dextromethorphan is to strengthen the Federal controls over the distribution of dextromethorphan in bulk.

SEC. 3. FOOD AND DRUG ADMINISTRATION; RESTRICTIONS ON DISTRIBUTION OF UNFINISHED ACTIVE INGREDIENTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351

et seq.) is amended by inserting after section 503A the following:

"SEC. 503B. RESTRICTIONS ON DISTRIBUTION OF UNFINISHED ACTIVE INGREDIENTS.

''(a) IN GENERAL.—If the Secretary determines that the distribution of an unfinished active ingredient should be restricted for the protection of the public health, the Secretary may by regulation prohibit the distribution of the ingredient to any person other than a person registered under section 510, subject to subsections (b) and (c).

''(b) FURTHER RESTRICTIONS.—Subsection (a) does not restrict the authority of the Secretary under section 201.122 of title 21, Code of Federal Regulations.

''(c) DEXTROMETHORPHAN.—Not later than 180 days after the date of the enactment of the Dextromethorphan Distribution Act of 2006, the Secretary shall issue a final rule under subsection (a) establishing restrictions on the distribution of dextromethorphan.

''(d) UNFINISHED ACTIVE INGREDIENT.—For purposes of this section, the term 'unfinished', with respect to an active ingredient, means an active ingredient that—

''(1) is one of the ingredients in a drug that is not in finished dosage form; or

''(2) is the sole ingredient of a drug that is not in finished dosage form.''.

(b) ENFORCEMENT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh) The distribution of an unfinished active ingredient in violation of regulations under section 503B.''.

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